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## PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)

05900002aa

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Application Number

09/994,937

Filed

November 28, 2001

on \_\_\_\_\_

First Named Inventor

Anderson

Signature \_\_\_\_\_

Art Unit

1616

Examiner

Webman

Typed or printed  
name \_\_\_\_\_

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).

Note: No more than five (5) pages may be provided.

I am the

☐ applicant/inventor.

☐ assignee of record of the entire interest.  
See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed.  
(Form PTO/SB/96)

☒ attorney or agent of record.  
Registration number 32,635

☐ attorney or agent acting under 37 CFR 1.34.  
Registration number if acting under 37 CFR 1.34 \_\_\_\_\_

Signature

Michael E. Whitham

Typed or printed name

703-787-9400

Telephone number

Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below\*.

☒ \*Total of 1 forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re patent application of

David M. Anderson

Confirmation No. 7327

Serial No. 09/884,937

Group Art Unit: No. 1616

Filed November 28, 2001

Examiner Webman

For SOLVENT SYSTEMS FOR PHARMACEUTICAL AGENTS

Commissioner for Patents  
PO Box 1450  
Alexandria, Virginia 22313-1450

**ATTACHMENT TO PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Sir:

This Pre-Appeal Brief Request for Review is being concurrently filed with a Notice of Appeal, a petition for a one month extension of time, and a pre-appeal brief request for review cover sheet. The Commissioner is authorized to charge any fees due for the extension of time and the notice of appeal to Attorney's Deposit Account 50-2041 (Whitham, Curtis, Christofferson & Cook).

*The Invention*

In the response filed December 15, 2006, the independent claims (1, 27, 52 and 53) were limited to composition or internally administerable solvent system which includes a structured fluid selected from the group consisting of a reversed cubic liquid crystalline phase and a reversed hexagonal liquid crystalline phase. The structured fluid includes (1) a polar solvent, (2) a lipid or surfactant, (3) an essential oil or dissolution/solubilization agent (selected from a specific group in claims 1 and 52; or having specific properties as specified in claims 27 and 53), and (4) a compound present in an effective amount in the structured fluid (e.g., a drug) that is less than 5% by weight soluble in soybean oil (in claims 52-53, the solvent system will be able to incorporate a compound in an effective amount which is less than 5% by weight soluble in soybean oil).

The application describes a system whereby difficult to solubilize drugs can be incorporated into a composition suitable for delivery to a patient. The

application discloses and claims certain ingredients which form a certain structure- a reversed cubic or reversed hexagonal liquid crystalline phase. Applicant has received a grant in Europe (European Patent 1 345 589) and Australia (Australian Patent No. 2002219878) on the subject matter of the present application.

*Errors and Omissions*

The Examiner has erroneously rejected claims 1, 3-19, 27, 29-44, 52, 53, 56, and 58-60 as failing to comply with the enablement requirement of 35 U.S.C. 112, first paragraph.

As noted in the amendment filed December 15, 2006, the application has been limited for the purposes of accelerating prosecution to reversed hexagonal liquid crystalline phase compositions (discussed in the application on page 24, lines 22 et seq.), not normal hexagonal phase liquid crystalline phase compositions (discussed in the application on page 23, line 12 et seq.), and to reversed cubic liquid crystalline phase compositions (discussed in the application on page 26, at line 17, et seq., and at page 28, at line 13 et seq.), not normal cubic liquid crystalline phase compositions (discussed in the application on page 25 at line 11 et seq.). Exemplary formulations are set forth on pages 52 et seq. of the patent application.

The Examiner has erroneously concluded that the specification does not enable one of ordinary skill in the art to make and use the invention and states "Nowhere in the specification do applicants disclose or claim the percent ranges of the claimed ingredients which will make the claimed species of structured fluid" (page 2 of the office action dated August 27, 2007).

This conclusion erroneously overlooks working examples set forth on pages 52-56 of the application, the detailed description of the materials set forth in the application on pages 4-51 of the application, the detailed discussion of the claimed reversed cubic phase materials set forth on pages 26 and 28 of the application, the detailed discussion of reversed hexagonal phase materials set forth on pages 23 and 24 of the application, and the declaratory evidence of David Anderson (filed December 15, 2006) and Richard Templer (filed June 7, 2007).

In short, the statement concerning percent ranges of the claimed ingredients made by the Examiner appears to overlook significant features of the

invention itself. That is, the inventor has found that difficult to solublize drugs (i.e., a compound that is less than 5% by weight soluble in soybean oil) can be present in an effective amount in a reversed cubic phase or a reversed hexagonal phase if those compositions also include certain identified co-solubilizers.

The patent specification and the declarations establish that

- one of ordinary skill in the art would know what a reversed cubic liquid crystalline phase and what a reversed hexagonal liquid crystalline phase is, and how to identify such phases

- see the application at pages 23, 24, 26, and 28
- see Templer declaration at section 7
- see Anderson declaration at sections 4 and 5

- one of ordinary skill in the art would know how to prepare the claimed reversed cubic liquid crystalline phase and reversed hexagonal liquid crystalline phase materials using certain identified co-solubilizers based on the patent specification, and one of ordinary skill in the art would know that the percentages of the ingredients used to achieve a reversed cubic [or reversed hexagonal] phase would vary depending on the nature of the compound of interest to be included therein

- see Templer declaration at section 10 where he sets forth steps A-H for preparing the claimed compositions and references passages of the application therein, as well as section 11 where he indicates that such steps are well within the skill and understanding of one of ordinary skill in the art.
- see also Templer declaration at section 9 where he sets forth basic criteria which would be understood by one of ordinary skill in the art.
- see Anderson declaration at section 5 for use of a phase diagram

- one of ordinary skill in the art would know that ingredients must be selected and combined and evaluated according to well established criteria, with precision, in order to achieve the formation of a reversed cubic liquid crystalline phase or reversed hexagonal liquid crystalline phase, and that mixing and matching any group of materials without precision will not produce the claimed invention.

- see Anderson declaration at section 3 where it is demonstrated

that the Lambert, Azuma and Benet references cannot be combined to produce the claimed invention

- see Templer declaration at section 11 corroborating the statements of Anderson
- the patent application provides a complete written description of the invention that would enable one of ordinary skill in the art to make and use the invention.
- see Templer declaration at sections 6 and 11

*New Issue Raised in the Office Action*

The Examiner states on page 2 of the office action that “It appears from item F on page 5-6 of the declaration (of Templer) that phase diagrams to make the claimed compositions are available in publications, raising the issue of whether applicant’s claimed invention is already known in the art.

This statement appears to confuse what a phase diagram is, and that which is stated by Dr. Templer.

Chapter 10 of The Colloidal Domain, referenced in section 5 of the Anderson declaration, and attached to the Anderson declaration provides a detailed discussion of phase diagrams. Page 3 of the Anderson declaration discusses the construction of the phase diagram of Figure 1 (Attached to the Anderson declaration the phase diagram shows that the combination of materials previously proposed by the Examiner do not make the claimed reversed cubic liquid crystalline phase or reversed hexagonal liquid phase-see also section 5 of the Anderson declaration).

With reference to page 5 of the Templer declaration, it is noted at section F that one of ordinary skill in the art would either consult publications or construct his or her own phase diagram. This statement is made in the context of practicing the invention taught by the applicant. No references of record illustrate or suggest the claimed invention. Dr. Templer’s declaration illustrates the familiarity one of ordinary skill in the art would have with phase diagrams, and illustrates how it would be well known for one of ordinary skill in the art to make and use the invention. With reference to section G of Dr. Templer’s declaration, it can be inferred that upon construction of a phase diagram, one of ordinary skill in the art

would know whether selected ingredients can form a reversed cubic liquid crystalline phase or a reversed hexagonal liquid crystalline phase, and the composition of the selected ingredients required for these phases. At no point does Dr. Templer state or suggest that the claimed invention is not new or unobvious. Among other things, the application describes certain co-solubilizers which can be used to permit the formation of reversed cubic and reversed hexagonal liquid crystalline phases. Rather, Dr. Templer's declaration established that the "application provides a complete written description of the invention that would enable one of ordinary skill in the art to make and use the invention" (see section 6 of the Templer declaration).

### *Conclusion*

The application provides ample teaching and description of the claimed invention which would enable one of ordinary skill in the art to make and use the claimed invention.

As the application provides a complete written description suitable for one of ordinary skill in the art to make and use the invention, and there are not references of record which anticipate or make obvious the claimed invention, it is requested that the position of the Examiner be reviewed, that the rejections be withdrawn, and that the application be passed to issue.

Respectfully submitted,



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